

## **REMARKS**

Applicants will address each of the Examiner's rejections in the order in which they appear in the Final Rejection.

### **Claim Rejections - 35 USC §102**

#### **Claims 19-20**

In the Final Rejection, the Examiner has withdrawn the prior rejections but now rejects Claims 19-20 under 35 USC §102(b) as being anticipated by Tay et al. (US 5,425,718) or Kelso et al. (US 5,186,712 - a new reference). Each of these rejections is respectfully traversed.

Initially, Applicants note that the Examiner previously rejected Claims 19-20 under 35 USC §102(b) as being anticipated by Tay et al. in the Final Rejection dated December 4, 2003. Applicants explained why the claims are patentable over this reference in Amendment D filed on April 30, 2004. The Examiner then withdrew the rejection in the Office Action of August 25, 2004. The Examiner now appears to again be making this rejection without reference to or explanation in response to Applicants' prior argument. Hence, Applicants respectfully submit that this rejection is erroneous and should be withdrawn. In order to advance the prosecution of this application, Applicants will explain why the claimed catheter is patentable over the cited references.

Independent Claim 19 is directed to a catheter for intraluminal treatment of a selected site in a body of a patient including a transfer device having a central opening for receiving the catheter and for storing at least one treatment element and propelling the treatment element into a lumen in the catheter. The catheter includes a connector integral with the proximal end of the catheter having at least one detent extending from the connector and having a transverse tab at the end of the detent

extending from the connector for securing the connector in the central opening of the transfer device by catching said tab inside said opening of the transfer device. This is shown, for example, in Fig. 41C of the present application at reference number 396. See also page 33, lns. 20-33 of the specification. The detent is manually actuatable to release the catheter from the central opening of the transfer device by depressing the detent so as to allow the transverse tab to be released from inside the opening of the transfer device. As explained below, neither of the cited references disclose or suggest such a device.

Tay et al.

Tay does not disclose or suggest the claimed catheter and connector. Unlike the catheter of the claimed invention, Tay is directed to a needle assembly. The concern in Tay is to prevent side and back stick incidents which occur when the needle is being inserted into the arterial system. Tay discloses a latching mechanism which has a finger-like projection 72 which extends from the housing 30 and a finger-like projection 74 which extends from a hub 50 of the needle. Projection 72 has a recess 75 with a tab 76 therein. Projection 72 has a touch pad 71 which acts as a release for the locking mechanism. The needle is only locked, however, when the hub 50 of the needle is pulled back into the housing 30. It is not engaged when the needle is pushed forward, allowing the distal end of needle to be pushed forward. See Col. 3, lns. 57-60 in Tay.

In contrast, the purpose of the structure of independent Claim 19 of the present application is so that the catheter cannot be separated from the transfer device until desired by the operator. As a result, no treating elements (which are typically radioactive) can escape from the central opening by the catheter being accidentally separated from the transfer device. This is very different than the

device of Tay, and accordingly, both devices have a different structure, work in a different manner and have a different purpose and objective. Hence, Tay is not relevant to the present invention.

Further, Claim 19 requires a transfer device having a central opening for receiving the catheter and storing at least one treatment device...In the Final Rejection, the Examiner alleges that 50 in Tay is a transfer device. However, Tay identifies 50 as a "hub". This hub is not a transfer device as in Claim 19. The hub also does not have an opening for receiving the catheter nor does it store a treatment element as in the claimed device.

The Examiner also contends that Tay discloses a detent 77 for securing the connector in the central opening of the transfer device (however, as explained above, there is no central opening or transfer device). Tay identifies 77 as tabs on projection 74. Projection 74 is located on hub 50. Projection 74 and tabs 77 are not part of a connector on the proximal end of a catheter nor do projection 74 and tabs 77 extend from such a connector, as in the device of Claim 19. Further, since projection 74 and tabs 77 are located on hub 50, they cannot secure a connector in the central opening of the transfer device (allegedly hub 50) by catching the tab inside the opening of the transfer device (i.e. if the projection and tabs are on hub 50, they cannot catch inside an opening (which does not exist) in hub 50 to secure a connector in an opening in hub 50).<sup>1</sup>

Therefore, Tay does not disclose or suggest the device of Claims 19 and 20 of the present application, and these claims are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

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<sup>1</sup> Similarly, Tay cannot disclose the detent comprising a cantilever arm axially extending from connector, as in dependent Claim 20.

Kelso et al.

Kelso also does not disclose or suggest the claimed invention.

Initially, Applicants note that Kelso has a completely different objective than the device of Claims 19 and 20. The connector with detent of these claims is provided as additional safety feature so that the catheter will not accidentally be removed from the transfer device. Rather, a coordinated effort is required by the operator. See e.g. page 33, lns. 4-11 and et seq. of the present application. This is intended so that the radioactive treatment elements used in the present invention do not escape from the catheter or transfer device and endanger the operator of the device.

In contrast, Kelso is directed to an intravenous catheter launching device. The objective of the Kelso device is "...whereby a simple release activity mechanically and automatically initiates such separation [between the catheter and the needle], thus enabling the user to easily and single-handedly initiate the installation of the catheter for infusion and other purposes" (col. 1, lns. 37-41) in order to launch the catheter and initiate separation of the catheter hub from the body (col. 1, lns. 62-68). There is no mention nor concern about radioactive treating elements. Hence, the objective of the two devices are different, one for easy quick single handed detachment (Kelso) and one for a much more secure attachment which requires a concerted effort to detach (Claims 19 and 20). As a result, the two devices have a different structure, operate differently and have a different purpose. Hence, Kelso is not relevant to the claimed invention.

Further, the Examiner identifies 57 in Kelso as a transfer device having a central opening 45. Kelso, however, states that 57 is opposite sides of body 3 and 45 is "a boss." The Examiner further states that 73 is a detent. Kelso identifies 73 as the tapered portion of triggers 12 with hook 73 on the end.

In contrast to Claim 19 of the present application, triggers 12 are not on a connector on the proximal end of a catheter, do not extend from such a catheter, and do not secure the connector in the central opening of a transfer device by catching a tab in the opening in the transfer device (since the triggers 12 are on sides 57 of body 3, they cannot secure a connector in an opening in body 3 by catching a hook inside an opening of body 3).<sup>2</sup>

Hence, Kelso does not disclose or suggest the device of Claims 19 and 20 of the present application, and those claims are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

Therefore, it is respectfully requested that the rejections of Claims 19 and 20 be withdrawn, and the claims allowed.

#### Claims 21, 42-43

Independent Claim 21 of the present application is directed to a catheter for intraluminal treatment of a selected site in a body by at least one treating element moveable by means of pressurized fluid. The catheter comprises first and second lumens extending between the proximal and distal ends of an elongated tube. The first and second lumens are in fluid communication with each other at a distal end of each lumen and the distal end of the elongated tube. The lumens are closed to outside the elongated tube (i.e. the catheter) at the distal end of the elongated tube or catheter. The first lumen is sized to slidably receive the treating element, and the second lumen has an elliptical cross section. Since the first lumen receives the treating element, the treating element

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<sup>2</sup> Similarly, Kelso cannot disclose the detent comprising a cantilever arm axially extending from connector, as in dependent Claim 20.

moves from the proximal to the distal end of the first lumen, via pressurized fluid, which is at the treatment area in the body. As the second lumen is in fluid communication with the first lumen, after treatment, the treating element returns to the proximal end of the catheter through the second lumen (i.e. the fluid return lumen). The first and second lumens are closed to outside the catheter at the distal end to keep the treating elements (which are typically radioactive) within the catheter at the distal end so that the treating elements are not released into the body but can be returned by the fluid return lumen. If the two lumens were not in fluid communication with each other at the distal end, the treating elements could not be transferred from the first lumen to the second or fluid return lumen after treatment had been affected. The second or fluid return lumen is made with an elliptical shape so that the area for fluid flow is increased without compromising the outer diameter of the catheter.

See e.g. page 35 of the present application.

In order to advance the prosecution of this application, Applicants have amended independent Claim 21 to make it clear that the first and second lumens are in fluid communication with each other at the distal end thereof and that each of these lumens is closed to outside the elongated tube at the distal end of the elongated tube.

#### Corvi

In the Final Rejection, the Examiner rejects Claims 21, 42-43 under 35 USC §102(b) as being anticipated by Corvi (US 5,879,499 - a new reference). This rejection is respectfully traversed.

More specifically, the Examiner cites Corvi as allegedly disclosing a catheter with first and second lumens extending between the proximal and distal ends of an elongated tube and in

communication with each other at the distal ends, with the first lumen sized to receive a treatment element and the second lumen 308 in an elliptical shape. Applicants respectfully disagree.

Applicants have reviewed Corvi and can find nothing therein which discloses or suggests a first lumen in fluid communication with lumen 308 at the distal ends of the lumens, and the Examiner has provided no indication in the Final Rejection as to where this feature is allegedly shown in the reference. As best as Applicants can determine, lumen 308 is the “third lumen”, and the third lumen is connected to an “occluding member 315” which appears to be some type of balloon. See cols. 57-58 and Figs. 85-87 of Corvi. There appears to be no fluid communication between lumen 308 and the other lumens in the Corvi device, in contrast to Claim 21 of the present application. The other two lumens in the Corvi device appear to have outlets to outside the elongated tube or catheter at the distal end of the catheter for infusing cardioplegic fluid to the patient’s aorta or for sensing pressure in the patient’s aorta. See cols. 57-58, especially col. 58, lns. 10-17 in Corvi. Hence, there are not two lumens closed to outside the elongated tube or catheter at the distal end of the elongated tube or catheter, as recited in Claim 21.

Therefore, Corvi fails to disclose or suggest the claimed invention, and independent Claim 21 and dependent Claims 42 and 43 are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Beil

The Examiner also rejects Claims 21, 42-43 under 35 USC §102(e) as being anticipated by Beil (US 6,146,354). This rejection is also respectfully traversed.

More specifically, the Examiner cites Beil as allegedly disclosing a catheter with first and second lumens extending between the proximal and distal ends of an elongated tube and in communication with each other at the distal ends, with the first lumen sized to receive a treatment element and the second lumen 148 in an elliptical shape. Applicants respectfully disagree.

Beil is directed to a multi-lumen catheter for treating a patient's blood. As a result, it has a first lumen for a guide wire, a second lumen for returning treated blood to a patient's blood vessel and a third lumen for extracting blood from the patient's blood vessel for treatment. See e.g. Abstract, and col. 3, lns. 54-61 in Beil. Clearly, in order to return blood to a patient's blood vessel and to extract blood from a patient's blood vessel, these lumens must be open to outside the elongated tube of the catheter at the distal end in order to perform these tasks, unlike the catheter recited in independent Claim 21 of the present application. Further, there is no disclosure or suggestion in Beil that the two lumens are in fluid communication with each other at the distal end of the lumens, as in Claim 21 (and the Examiner has not cited anywhere in the reference where this is allegedly shown). In fact, the two lumens could not be in fluid communication, or the treated blood would not be able to reach the patient's blood vessel where it is so desperately needed as it would just continue to recycle in the catheter. Further, blood to be treated could not be retrieved from the blood vessel if the two lumens were in fluid communication.

Therefore, Beil fails to disclose or suggest the claimed invention, and independent Claim 21 and dependent Claims 42 and 43 are patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

Rejection of Claim 22

The Examiner also rejects Claim 22 under 35 USC §103(a) over Corvi or Beil in view of Fiddian-Green (US 6,334,064). This rejection is also traversed.

This dependent claim is at least patentable over the cited references for the reasons described above for independent Claim 21.

Further, Fiddian-Green is directed to a remote sensing tonometric catheter which is very different than a catheter for use in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element, as in the claimed invention. Further, the catheter in Figs. 1-2 of Fiddian-Green appears to have a single lumen extending from the proximal end to the distal end of an elongated tube. The lumens of Figs. 4 are explicitly stated as being noncommunicating with each other (see col. 6, lns. 40-44 in Fiddian-Green). The lumens of Figs. 5 are merely connected with a catheter at the end of the lumen, not in communication with another lumen which extends from the proximal end to the distal end of the elongated tube.

Additionally, Fiddian-Green does not disclose or suggest "at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of the patient, said radiopaque marker being located within said first lumen at said distal end and providing a fluid flow path between said first and second lumen," as recited in Claim 22. Instead, Fiddian-Green discloses a radiopaque tungsten plug which is intended to "block" the lumen, or a radiopaque tungsten rod which terminate the end of the lumen. See Col. 7, lns. 20-34 of Fiddian-Green. Hence, the reference does not disclose or suggest a radiopaque marker that provides a fluid path between the first and second lumens.

Therefore, for at least the above-stated reasons, Claim 22 is not disclosed or suggested by the cited references and is patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Rejection of Claims 38-39

The Examiner also continues to reject Claims 38-39 under 35 USC §103 as being unpatentable over Waksman et al. (US 5,899,882) and further in view of Littmann et al. (US 6,088,610). This rejection is also respectfully traversed.

While this rejection is respectfully traversed for at least the reasons discussed in Applicants' prior responses, in order to advance the prosecution of this application, Applicants have amended Claim 38 to include the feature of dependent Claim 39 (now canceled) that the guidewire lumen lining comprises a blend of a high density polyethylene and a low density polyethylene. The Examiner acknowledges that Waksman does not disclose this feature and still does not explain where Littman allegedly discloses this feature. Applicants respectfully submit that neither reference discloses or suggests this feature.

Therefore, for at least the above-stated reasons, Claim 38 is not disclosed or suggested by the cited references and is patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

New Claim

Applicants are adding new dependent Claim 44 herein. This claim is patentable over the cited references for at least the reasons discussed above for independent Claim 19. Accordingly, it is respectfully requested that it also be allowed.

If any fee should be due for this claim, please charge our deposit account 50/1039.

Information Disclosure Statement

Applicants are also submitting an information disclosure statement (IDS) herewith. It is respectfully requested that this IDS be entered and considered prior to the issuance of any further action on this application.

If any further fee should be due for this IDS, please charge our deposit account 50/1039.

Conclusion

Therefore, for at least the above-stated reasons, the present application is in an allowable condition and should be allowed.

Please charge our deposit account 50/1039 for any further fee for this amendment.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,



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